

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

**UNITED STATES OF AMERICA ex
rel. LEIGH H. CAMPOS,**

Plaintiffs,

v.

**3RD PARTY API LLC, LENNICK
HOLDINGS, INC. d/b/a 3RD PARTY
API, BRYAN LENETT, MICHAEL
MUCHNICK, PERFORMIX
SPECIALTY PHARMACY, LLC,
AND 3RD PARTY SERVICES OF
FLORIDA CORP.,**

Defendants.

**COMPLAINT IN PARTIAL
INTERVENTION OF THE
UNITED STATES OF AMERICA**

Case No. 20-cv-206-JL

JURY TRIAL DEMANDED

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

v.

**3RD PARTY SERVICES OF
FLORIDA CORP., GEORGINA
EXPOSITO, PERFORMIX
SPECIALTY PHARMACY LLC
D/B/A GRANITE STATE
COMPOUNDING AND FAMILY
WELLNESS, and GRANITE STATE
COMPOUNDING AND FAMILY
WELLNESS, LLC, N/K/A GRANITE
STATE COMPOUNDING &
WELLNESS PHARMACY, LLC,**

Defendants.

1. The United States of America (the “Government”) brings this action on behalf of the United States Department of Health and Human Services (“HHS”) and the United States

Department of Defense, agencies of the United States, seeking damages and penalties against the defendants, 3rd Party Services of Florida Corp., (“3rd Party Services of Florida”), Georgina Exposito, PerforMix Specialty, LLC, d/b/a Granite State Compound and Family Wellness (“PerforMix”), Granite State Compound and Family Wellness, LLC, n/k/a Granite State Compounding and Wellness, Pharmacy, LLC (“Granite State Compounding”) under the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, and, in the alternative, under the common law for unjust enrichment, in connection with their billing federal health care programs for false claims based on falsified medical diagnoses.

2. 3rd Party Services of Florida was a company, wholly owned and controlled by Georgina Exposito, which provided a service of obtaining prior authorizations on behalf of pharmacies for prescription drugs, to enable the pharmacies to be paid by insurance providers including Medicare Part D and TRICARE for those drugs. Starting no later than March 2018, defendant 3rd Party Services of Florida and its owner, defendant Georgina Exposito, made and/or caused to be made, false and fraudulent statements to Medicare Part D and TRICARE sponsors/pharmacy benefit managers on behalf of PerforMix and other pharmacies such as MP Pharmacy, to secure expeditious prior authorizations for prescription drugs by altering patients’ medical diagnoses. 3rd Party Services either contracted directly with the pharmacy or contracted with an intermediary, 3rd Party API, which then subcontracted the prior authorization work to 3rd Party Services.

3. This resulted in defendants submitting, or causing to be submitted in 2018 and 2019, false claims to Medicare Part D and TRICARE for prescription drugs on behalf of PerforMix and those other pharmacies, given that these claims were based on falsely acquired prior authorizations.

4. Finally, PerforMix, which now has continued to do business as Granite State Compounding, became aware no later than April 2019 that it wrongfully received Medicare Part D and TRICARE payments for prescription drugs based on false diagnoses in the prior authorizations secured by 3rd Party Services, yet took no steps to return these overpayments to the Government, let alone within 60 days, as required by law.

JURISDICTION AND VENUE

5. The jurisdiction of this Court is founded upon 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. § 3730.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

PARTIES

7. Plaintiff is the United States of America suing on its own behalf and on behalf of (1) the HHS, and its component agency, the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare Program ("Medicare"), and (2) The Defense Health Agency, which administers the TRICARE Program ("TRICARE").

8. Defendant 3rd Party Services of Florida was a Florida corporation wholly owned and controlled by defendant Georgina Exposito, a resident of Miami, Florida.

9. Defendant PerforMix is a compounding pharmacy and a New Hampshire LLC, with a principal place of business located at 105 Ponemah Rd, Amherst, NH 03031.

10. PerforMix currently continues to operate its compounding pharmacy business through an entity newly formed in 2023, Defendant Granite State Compounding. It is also a New Hampshire LLC with a principal place of business located at 105 Ponemah Rd, Amherst, NH 03031.

FEDERAL HEALTH CARE PROGRAMS

Medicare

11. Medicare is a federal health care program that provides federally subsidized health insurance for persons who are 65 years or older or are disabled. *See* 42 U.S.C. §§ 1395 et seq. ("Medicare Program"). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries.

12. HHS, through its component agency, CMS, contracts with private companies ("Part D sponsors") authorized to sell Part D insurance coverage ("Part D plans"). Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors, in turn, enter into subcontracts with pharmacies, either directly or through a pharmacy benefits manager ("PBM"), to provide drugs to Medicare Part D beneficiaries enrolled in their plans.

13. After a physician writes a prescription for a Medicare Part D beneficiary, the patient can fill the prescription at a pharmacy. When the pharmacy dispenses drugs to that Part D beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through a PBM). The pharmacy receives reimbursement from the Part D sponsor (or the PBM) for the portion of the drug cost not paid by the beneficiary.

14. The Part D sponsor then is required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and the product service identifier for the Part D drug that was dispensed. Each PDE that is submitted to CMS by the Part D

sponsor is a summary record that documents the final adjudication of a dispensing event based upon claims received by the sponsor from pharmacies. The PDE records are used by CMS to calculate risk-sharing and reconcile reinsurance and low-income cost-sharing subsidy payments to Part D sponsors. *See* 42 C.F.R. §§ 423.336(c) and 423.343(c) and (d). Submitting PDE data to CMS, which is necessary for CMS to determine the amount of payments to Part D sponsors for qualified drug coverage, is a condition of CMS' payments to Medicare Part D sponsors. *See* 42 C.F.R. § 423.322. CMS payments are made from the Medicare Prescription Drug Account. *See* 42 C.F.R. § 423.315(a).

15. Under Medicare Part D, CMS makes monthly prospective payments to each Part D plan, which covers three subsidies: direct subsidy, reinsurance subsidy, and low-income cost-sharing subsidy. *See* 42 C.F.R. §§ 423.315, 423.329. The payment amounts are based on information in the approved basic bid and on data provided by CMS that update payments throughout the year. These data include enrollment dates, low-income subsidy eligibility, risk adjustment scores and other data. Some data (e.g., enrollment dates and low-income subsidy status) may change throughout the year, which results in monthly adjustments to prior payments. After the end of the payment year, CMS reconciles the prospective payments paid to each Part D plan with the actual costs the plan has incurred. During reconciliation, CMS compares the finalized prospective payments and the corresponding actual costs reported on PDE records and makes payment adjustment according to the rules for each payment methodology. Payment adjustment can be positive or negative. If the reconciliation amount is positive, the actual amount incurred exceeded the amount paid prospectively, and the plan is entitled to additional payment. If the reconciliation amount is negative, the actual amount incurred was less than the amount paid prospectively, and the plan pays the reconciliation amount. The payments made by CMS to the

Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

16. In order to receive Part D funds from CMS, the Part D sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, including the FCA, and CMS instructions. *See* 42 C.F.R. § 423.505(h)(1); 42 U.S.C. § 1860D-12(b)(1). By statute, all contracts between a Part D sponsor and HHS must include a provision whereby the Plan D sponsor agrees to comply with the applicable requirements and standards of the Part D program, as well as the terms and conditions of payment governing the Part D program. *See* 42 U.S.C. § 1395w-112. Further, CMS regulations expressly require Part D sponsors to certify, in their contracts with CMS, that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA. *See* 42 C.F.R. § 423.505(h)(1).

17. Accordingly, all contracts entered into between CMS and Plan D sponsors include a provision in which the sponsor "agrees to comply with ... federal laws and regulations designed to prevent ... fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729 et seq.), and the anti-kickback statute " Further, CMS regulations also expressly require that all subcontracts between Part D sponsors and downstream entities including pharmacies - contain language obligating the pharmacies to comply with all applicable federal laws, regulations, and CMS instructions. *See* 42 C.F.R. § 423.505(i)(4)(iv). CMS regulations also require fraud, abuse, and waste training for all Part D sponsors, downstream entities, and their employees and managers. 42 C.F.R. § 423.504.

18. CMS regulations further require Part D sponsors to certify to the accuracy, completeness, and truthfulness of the PDE claims data submitted to CMS. 42 C.F.R. § 423.505(k).

19. With regard to submitting PDEs in particular, Part D sponsors and their subcontractors must certify that all claims are true and accurate. 42 C.F.R. § 423, 404(k)(3); and CMS Prescription Drug Benefit Manual, Chapter 9 - Part D Program to Control Fraud, Waste, and Abuse, Section 80.1, p. 67 (citing 42 C.F.R. §423.505(k)(3)); see also “Prescription Drug Benefit Manual, Chapter 9 - Part D Program to Control Fraud, Waste, and Abuse,” p. 16, Section 40-2 (citing 42 C.F.R. § 423.505(k)(3)) (“CMS requires that any entity that generates [Part D] claims data on behalf of a Sponsor” must both “certify to CMS the accuracy, completeness, and truthfulness of that data,” and “acknowledge that the data will be used for purposes of obtaining Federal reimbursement.”)

20. With regard to pharmacies and other subcontractors participating in the Part D program, CMS regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

TRICARE

21. TRICARE is a federal health care program established by federal law. 10 U.S.C. § 1071-1110b. TRICARE covers eligible beneficiaries, which, inter alia, includes active-duty members of the Uniformed Services and their dependents as well as retired members of the Uniformed Services and their dependents. TRICARE is administered by the Defense Health Agency.

THE FALSE CLAIMS ACT

22. The FCA is the primary civil remedial statute designed to deter fraud upon the United States and reflects Congress' objective to enhance the Government's ability to recover losses as a result of fraud against the Government. S. Rep. 99-345 (1986), at 1, as reprinted in 1986 U.S.C.C.A.N. 5266.

23. First, a defendant violates the FCA when it "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). As it relates to this case, the term "claim" under § 3729(b)(2) of the FCA includes "(A) . . . any request or demand, whether under a contract or otherwise, for money . . . that . . . (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government - (I) provides or has provided any portion of the money . . . requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money which is requested or demanded." *Id.* § 3729(b)(2).

24. Second, a defendant violates the FCA when it "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).

25. Third, a defendant violates the FCA when it "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." *Id.* § 3729(a)(1)(G).

26. Section 6402(a) of the Patient Protection and Affordable Care Act of 2010 (Enhanced Medicare and Medicaid Program Integrity Provisions), Pub. L. No. 111-148, 124 Stat. 119, 753-56 (2010), amended the Social Security Act by adding a new provision that addresses what constitutes an overpayment under the FCA in the context of a federal health care program. Under this section, an overpayment is defined as “any funds that a person receives or retains under Title XVIII or XIX to which the person, after applicable reconciliation, is not entitled.” *See* 42 U.S.C. § 1320a-7k(d)(4)(B). In addition, this provision specifies in relevant part that an “overpayment must be reported and returned” within “60 days after the date on which the overpayment was identified.” *Id.* § 1320a-7k(d)(2).

27. Failure to return any overpayment, such as each of the claims on which PerforMix received an overpayment from Medicare as result of the false diagnoses submitted by Georgina Exposito and her company, constitutes a reverse false claim actionable under section 3729(a)(1)(G) of the FCA.

28. Under the FCA, the terms “knowing” and “knowingly” include “actual knowledge of the information,” deliberate ignorance of the truth or falsity of the information, or reckless disregard of the truth or falsity of the information, and require no proof of specific intent to defraud. 31 U.S.C.A. § 3729(b)(1)(A),(B). Congress intended the terms “knowing” and “knowingly” to “reach what has become known as the ‘ostrich’ type situation where an individual has ‘buried his head in the sand’ and failed to make simple inquiries which would alert him that false claims are being submitted.” S. Rep. No. 99-345 (1986), at 21, as reprinted in 1986 U.S.C.A.N. 5266, 5286 (quotations in original.) “It is intended that persons who ignore ‘red flags’ that the information may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim should be held liable under the Act.” H. Rep. No.

99-660, at 21 (1986) (to accompany False Claims Act of 1986, H.R. 4827). As used in this Complaint, the terms “knowing” and “knowingly” have the meaning ascribed to them by the FCA, as do their derivatives “knowledge,” “known,” and “knew.”

29. The term “material” as used in the FCA, “means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

30. The FCA imposes liability of treble damages plus a civil penalty for each false claim in an amount not less than \$13,846 and no more than \$27,894, which is statutorily adjusted for inflation each successive year under the Bipartisan Budget Act of 2015, Pub. L. 114-74, § 701, 129 Stat. 584, 599-601 (2015). See 31 U.S.C. § 3729(a)(1).

THE DEFENDANTS’ CONDUCT

I. Prior Authorization Fraud by 3rd Party Services of Florida and Georgina Exposito

A. Prior Authorization Process

31. Part D sponsors or PBMs may employ utilization management rules that require providers to obtain “prior authorization” from the sponsor for certain drugs. This applies to TRICARE as well. This means that the plan will pay for the cost of the drug only if the prescribing physician provides information establishing that certain criteria have been met.

Prior authorizations should be required by a Medicare Part D sponsor or PBM when there is a “high likelihood of use for non-medically accepted indications. Prescription Drug Benefit Manual, Ch. 6, §§ 30.2.2.1-30.2.2.2. “A drug approved or denied through prior authorization constitutes a coverage determination.” Prescription Drug Benefit Manual, Ch. 6, § 20.2.2.

32. Clinical criteria must be met in order to secure prior authorization for certain drugs. Part D plans and TRICARE typically require the prescriber to provide information regarding the

patient's medical condition and/or diagnosis before a determination is made as to whether the drug will be covered. The requested medical information is supposed to be provided by the prescribing physician, or someone from his or her office, to ensure that it is accurate, and that the prescription is medically necessary.

33. Part D sponsors rely on the representations made regarding the patient's medical condition and diagnosis to make coverage determinations.

34. Many of the drugs regularly filled by PerforMix and the other pharmacies that 3rd Party Services worked for, often required prior authorization, including the topical drugs Doxepin, Diclofenac, and Lidocaine. These drugs are common ingredients in compounded topical pain creams, and which HHS OIG previously flagged as expensive and potentially linked to fraud. *See* OEI-02-16-00290, High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns (June 2016), <https://oig.hhs.gov/oei/reports/oei-02-16-00290.pdf>; and OEI-02-16-00440, Questionable Billing for Compounded Topical Drugs in Medicare Part D (August 2018), <https://oig.hhs.gov/oei/reports/oei-02-16-00440.pdf>.

B. The Scheme

35. Georgina Exposito and her company 3rd Party Services of Florida were paid by pharmacies, including PerforMix, to obtain prior authorizations from insurance programs including Medicare and TRICARE so that their claims for reimbursement for the filled drugs would be paid.

36. 3rd Party Services of Florida either provided these services directly to the pharmacy, or they provided it as a subcontractor for another company that contracted with the pharmacy. MP Pharmacy is an example of a pharmacy with which 3rd Party Services of Florida directly

contracted. Defendant PerforMix is an example of a company that 3rd Party Services of Florida provided these services for as a subcontractor.

37. In PerforMix's case, it engaged an intermediary company called 3rd Party API, which made the initial contact with PerforMix as it did with several other pharmacies. 3rd Party API acted largely as a reseller as it did not perform prior authorizations itself but, in turn, contracted with 3rd Party Services of Florida, which actually performed the prior approval services.

38. In either case, 3rd Party Services charged a fee for each prior approval it submitted and an additional fee for every successful approval. This incentivized Georgina Exposito and 3rd Party Services to process as many successful prior approvals as fast as they could.

39. Georgina Exposito, knowing that only certain diagnoses would result in approved prior authorizations, engaged in a scheme to fraudulently alter the diagnoses made by prescribing providers in order to obtain approval for the prior authorizations and to maximize the number of prior approvals her company could process and that she could receive.

40. Georgina Exposito directed her employees to change the diagnosis codes to ones that could be communicated to the insurance plans/PBMs and result in approvals of the prior authorizations.

41. Georgina Exposito also gave her employees a script to follow when communicating with the insurance plans or PBMs. The script directed them to answer the question as to whether the drug was prescribed for an FDA approved indication as "always yes." This direction was given by Exposito even though she knew full well that this was not true as she was directing the diagnoses to be altered.

42. 3rd Party Services of Florida employees followed these directions, altering the diagnosis codes associated with claims for prescriptions, and making false statements to the insurance

plans and/or the PBMs. This resulted in the improper approval of prior authorizations, and consequently the payment of false claims for those drugs.

43. Medicare Part D sponsors and TRICARE would not have approved the prior authorizations for coverage of the prescribed drug, had they known, that 3rd Party Services of Florida, on behalf of the pharmacy, fabricated the patient's diagnoses, and thereby concealed that the prescriptions were actually for non-covered uses.

44. The scheme often involved falsified prior authorizations for topical Lidocaine, Doxepin, and Diclofenac, where prescriptions for chronic pain or similar diagnoses were altered to diagnoses like pruritis, actinic keratosis or sunburn, so that they would be approved by the PBM and the Part D sponsor.

45. For example, on June 27, 2018, a Medicare Part D beneficiary, "RS," filled a prescription for Diclofenac 3% gel at PerforMix. The patient's diagnosis code was M54.5, which is lower back pain. 3rd Party Services of Florida handled the prior authorization on behalf of PerforMix. Specifically, on June 27, 2018, Maggie Quintana, an employee of 3rd Party Services of Florida spoke to a representative of the PBM, OptumRX, and conveyed that RS's diagnosis was for actinic keratosis. Diclofenac 3% gel is indicated for actinic keratosis, not for lower back pain and the PBM/Part D sponsor would not have approved the prior authorization for a lower back pain diagnosis. The PBM and Medicare Part D sponsor approved the prior authorization on June 27, 2018, because of 3rd Party Services' misrepresentations. 3rd Party Services and PerforMix caused to be presented false or fraudulent claims and used false records or statements material to false claims to be presented to Medicare, in violation of the FCA.

46. Similarly, on July 16, 2018, a TRICARE beneficiary, "CB" filled a prescription for Diclofenac at PerforMix. The patient's diagnosis code was M54.16, *i.e.*, lumbar radiculopathy.

3rd Party Services of Florida handled the prior authorization on behalf of PerforMix. Maggie Quintana falsely conveyed to TRICARE that the diagnosis was for actinic keratosis. 3rd Party Services and PerforMix thus caused to be presented false or fraudulent claims and used false records or statements material to false claims to be presented to TRICARE in violation of the FCA.

47. The scheme was not confined only to PerforMix. For example, on or about September 13, 2018, Medicare Part D beneficiary “MS” filled a prescription at MP Pharmacy for lidocaine 5% ointment. MS’s diagnosis was M81.0 for age-related osteoporosis. However, 3rd Party Services misrepresented the diagnosis to the PBM, CVS Caremark, on a phone call on September 13, 2018 as W57.XXA, *i.e.*, an insect bite, in order to secure the prior approval and payment of the claim.

48. The PBM and Medicare Part D Plan approved the prior authorization on September 13, 2018 because of 3rd Party Services’ misrepresentations. 3rd Party Services and Performix caused to be presented false or fraudulent claims and used false records or statements material to false claims to be presented to Medicare and TRICARE, in violation of the FCA.

C. PerforMix’s False Claims Act Liability

49. PerforMix had a low success rate, of no more than approximately 20%, in obtaining prior authorizations before 3rd Party Service of Florida began handling them. Also, the PA approval process was burdensome and time consuming for both the pharmacy and issuing provider.

50. PerforMix contracted with 3rd Party API in early March 2018, and in turn engaged 3rd Party Services to perform the actual prior authorization work.

51. PerforMix advertised its partnership with 3rd Party API to the prescribing physicians as time-saving and that it would lead to a 50% or above approval rate. The prescribing physicians

then authorized 3rd Party API (and in effect its agent 3rd Party Services of Florida) to handle prior authorizations for their patients.

52. PerforMix sent the prescriptions to be submitted for prior authorizations by their agents, 3rd Party API/3rd Party Services of Florida, without providing any oversight over what was being submitted or said to obtain prior authorizations, despite being promised a very high success rate that it had not encountered previously.

53. The approval rate did go up by May 2018 to around 50% for the prior authorizations submitted by 3rd Party Services of Florida, which PerforMix just accepted without checking or asking for any type of records to validate that the correct diagnoses were being submitted.

54. Additionally, there was a corresponding explosion of billing at that time. For example, PerforMix obtained approximately \$14,000 from Medicare Part D for Diclofenac in December 2017, *i.e.*, before 3rd Party Services began to handle PerforMix's prior authorizations. By June 2018, that number rose to over \$90,000 for that month.

55. PerforMix's ownership acknowledged in a September 2018 internal email that prior authorizations "stand for a substantial amount of [its] business."

56. No later than February of 2019, PerforMix's staff and owners became aware of complaints that the wrong diagnosis was being submitted to obtain prior approvals. This occurred when PBMs and Part D sponsors had questions about particular diagnoses, and reached out to the provider to discover that the prescription was for a completely different diagnosis.

57. For example, one insurer called the prescribing medical provider with questions about a prior authorization request for an 89-year-old patient that purportedly had a diagnosis for sunburns and insect bites. This was obviously suspicious which led to the call to the doctor's

office and the discovery that the actual diagnosis was for chronic pain. Someone from the prescribing doctors' office then notified PerforMix.

58. In February 2019, when these complaints first started, a PerforMix staff member brought to the attention of PerforMix's managers and owners that this could be part of a scheme to defraud insurance and suggested an audit of the prior approval submissions.

59. No such audit was undertaken. Instead, PerforMix continued to allow 3rd Party Services of Florida to submit prior authorization approvals without any oversight by PerforMix for approximately another two months. During that time, additional false claims were submitted to the government on PerforMix's behalf by its agents.

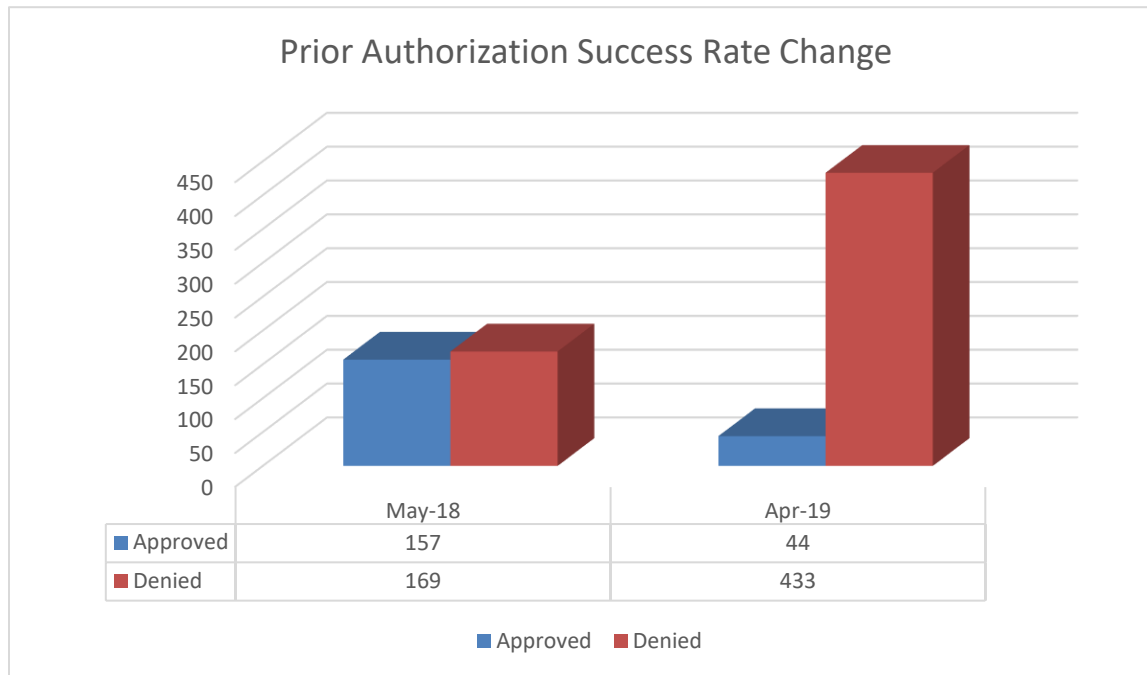
60. For example, in or about March 2019, patient and Medicare Part D beneficiary FM obtained a prescription for Diclofenac 3% gel. 3rd Party Services handled the prior authorization. The patient's diagnosis was M17.11, osteoarthritis of the knee, which 3rd Party Services of Florida changed to Actinic Keratosis. This induced the PBM and Part D sponsor to approve the prior authorization on or about March 27, 2019, causing the claim to be paid.

61. Through April 2019, PerforMix continued to get further complaints of altered diagnoses submitted to the PBMs. PerforMix's managers and owners, including owner and director of pharmacy James Tomacchio, Sr., and pharmacist, manager, and current owner Natalie Cote, were aware of these further reports of altered diagnoses.

62. Finally, starting on or about April 3, 2019, Natalie Cote spoke to Georgina Exposito to institute some oversight over 3rd Party Services of Florida's prior approval submissions in light of the altered diagnoses.

63. At this time, PerforMix saw a dramatic drop in successful prior approvals from the approximately 50% approval rate that 3rd Party Services promised and produced to a mere 10%

success rate in April 2019. For example, comparing May 2018, a month with no oversight, to April 2019, when oversight started, shows that dramatic change as follows:



64. This drastic change once PerforMix instituted some oversight put it on notice that many of the previous successful prior authorizations were based on false diagnoses.

65. There was also therefore a large drop in Medicare Part D billing for those drugs that required prior authorizations. For example, PerforMix obtained over \$90,000 in Medicare Part D payments for Diclofenac in May 2018, which dropped down to just over \$6,000 by June 2019.

66. Additionally, PerforMix, including Natalie Cote, was notified by a PerforMix pharmacy technician by email on April 22, 2019 that one drug, Diclofenac gel, would only be approved for a diagnosis of Actinic Keratosis, while another, Doxepin, would only be approved for dermatitis. PerforMix and Natalie Cote were aware that those drugs were largely prescribed for general pain, and therefore Cote responded by email that day writing “Wow, makes me wonder how we ever got an approval on them in the past lol.” To which the technician responded, “I have a few ideas . . . lol.”

67. No later than the time this email was circulated, PerforMix had clear knowledge that prior approvals for at least those two drugs were likely based on false diagnoses, and that consequently, PerforMix should not have received Medicare Part D and TRICARE payments for those prescriptions. Despite this knowledge, neither Natalie Cote nor other owners or managers at PerforMix, ever performed an audit of the prior authorizations submitted by 3rd Party Services of Florida, nor attempted to contact CMS about overpayments.

D. PerforMix Continues Operating Under a New Name

68. On July 27, 2023, soon after its principals became aware of the FCA investigation and were interviewed as part of that investigation, PerforMix registered a new trade name, Granite State Compounding and Family Wellness.

69. Starting with registering the trade name, PerforMix's principals began to take steps to begin operating PerforMix under a new name, and eventually as a "new" entity.

70. James Tomacchio, Sr. was one of the original owners of PerforMix. He was also Head of Pharmacy.

71. Natalie Cote was a pharmacist and manager of PerforMix, who in April 2021 obtained an ownership interest in PerforMix through a company owned by her and her husband.

72. On February 27, 2024, James Tomacchio, Sr. filed a consent for his wife Roberta Tomacchio and Natalie Cote to use PeforMix's trade name Granite State Compounding and Family Wellness for a "new" entity.

73. On March 18, 2024, Natalie Cote signed and filed a Certificate of Formation for Granite State Compound and Family Wellness, LLC, with herself and Roberta Tomacchio as the managing members. Natalie Cote listed her email address, NCote@performix.com, in the filing as the email address for the "new" entity.

74. The “new” entity has the same address for its principal place of business as PerforMix and continues to operate as a compounding pharmacy.

75. At the time of its formation, Natalie Cote continued on as pharmacist and manager and James Tomacchio, Sr., as the director of pharmacy.

**COUNT ONE - FALSE CLAIMS ACT: PRESENTATION OF FALSE CLAIMS
(31 U.S.C. § 3729(a)(1)(A))**

76. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

77. The Government seeks relief against Defendants under Section 3729(a)(1) of the FCA, 31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

78. Through the acts set forth above, Defendants knowingly, or acting with deliberate ignorance or reckless disregard for the truth, presented, or caused to be presented, false or fraudulent claims for payment to Medicare and TRICARE relating to the sale of medications.

79. The Government through Medicare Part D and TRICARE made payments to Plan D sponsors or Defendant PerforMix or to other pharmacies, because of defendants’ false or fraudulent claims.

80. By virtue of the said false or fraudulent claims, the United States has incurred damages in a substantial amount to be determined at trial and, is entitled to treble damages under the FCA, plus a civil penalty for each violation of the Act.

**COUNT TWO - FALSE CLAIMS ACT: USE OF FALSE STATEMENTS
(31 U.S.C. § 3729(a)(1)(B))**

81. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

82. The Government seeks relief against Defendants under Section 3729(a)(1)(B) of the FCA.

83. Through the acts set forth above, Defendants knowingly, or acting with deliberate ignorance or reckless disregard for the truth, made, used, and caused to be made and used, false records and statements material to false or fraudulent claims in connection with the sale of medications.

84. The Government through Medicare Part D and TRICARE made payments to Plan D sponsors or Defendant PerforMix or to other pharmacies, because of defendants' false or fraudulent claims.

85. By virtue of the said false or fraudulent claims, the United States has incurred damages in a substantial amount to be determined at trial, and is entitled to treble damages under the FCA, plus a civil penalty for each violation of the Act.

**COUNT THREE - FALSE CLAIMS ACT: REVERSE FALSE CLAIMS
(31 U.S.C. § 3729(a)(1)(G))**

86. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

87. Defendants PerforMix and Granite State made and used or caused to be made or used false records or statements material to an obligation to pay or transmit money to the United States, or knowingly concealed, avoided, or decreased an obligation to pay or transmit money to the United States.

88. Such false records or statements or knowing concealment, avoidance or decrease of an obligation to pay or transmit money to the United States were made or done knowingly, as defined in 31 U.S.C. § 3729(a)(1).

COUNT FOUR - UNJUST ENRICHMENT

89. The Government incorporates by reference all paragraphs of this complaint set out above as if fully set forth.

90. By receiving payments from the Government based on the foregoing conduct, PerforMix and Granite State were unjustly enriched. The circumstances of the receipt of these payments are such that, in equity and good conscience, the defendants should not retain these payments, the amount of which is to be determined at trial.

THEREFORE, the plaintiff United States of America respectfully requests this Court to:

- A. Enter judgment for the plaintiff and against the defendants as follows:
 - (i) Counts One to Three – An amount equal to three times the loss sustained by the United States, plus penalties per false claim, representation, or overpayment as provided in 31 U.S.C. § 3729(a), plus award the United States its costs;
 - (ii) Count Four - An amount to be determined at trial, together with costs and interest; and
- B. Grant such other and further relief as is just and proper.

Respectfully submitted,

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